JUL - 9 2001

510(k) Summary

General Information: K011092

This 510(k) is to provide notification of substantial equivalence for the Candela SPTL-1e Pulse Dye Laser System, which is substantially equivalent to previously marketed devices intended for the photocoagulation of benign cutaneous lesions, such as warts, scars, striea and psoriasis; benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, poikiloderma of Civatee and in gynecology.

Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, SPTL - 1e Pulse Dye Laser System
Predicate Devices:	Candela SPTL-1b Pulse Dye Laser (K001093), Candela Long Pulsed Dye Laser (K993671) and the Candela SPTL Long Pulse/Tunable Pulse Dye Laser (K954934)

Description:

The SPTL-1e Pulse Dye laser is a 585 nm pulsed, flash lamp excited dye, medical laser, controlled by an embedded microprocessor, to be used for the treatment of psoriasis, telangiectasia, port wine stains, benign cutaneous lesions and other benign cutaneous vascular lesions. The laser system may be used with the Candela Dynamic Cooling Device, which provides a short burst of cryogen spray prior to firing the laser pulse. The laser output energy is delivered via an optical fiber to a handpiece, which produces circular beams with diameters of 7 and 10 millimeters on the skin. The cryogen, which is housed within the laser enclosure, is delivered via a hose to a nozzle located in the handpiece.

The Candela SPTL-1e Pulse Dye Lasers are equipped with safety interlock systems to protect patients and operators. Users of the device make selections from an onboard control panel to regulate operation during treatment.

Testing:

As a laser product, the SPTL-1e Pulse Dye Laser is required to conform and does conform to the Laser Performance Standard (21 CFR 1040). In addition the device conforms to the UL 544 electrical safety standard and the Essential Requirements of the European Union Medical Device Directives.

Summary of Substantial Equivalence:

The Candela SPTL-1e Laser has the same intended use, utilizes similar operating principles and matches key design aspects, including similar spot size, the same wavelength and / or the same maximum delivered power as the predicate devices.

On the basis of similarities in methods of assembly, method of operation, and intended uses, Candela believes that its Candela SPTL - 1e Laser System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Joan M. Clifford
Director, Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K011092
Trade/Device Name: Candela SPTL - 1e Pulse Dye Laser System
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: April 9, 2001
Received: April 10, 2001

Dear Ms. Clifford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011092

Device Name: Candela *SPTL - 1e* Pulse Dye Laser System

Indications For Use:

The Candela SPTL-1f Pulse Dye Laser is indicated for the following uses:

General Surgery: Photocoagulation of benign cutaneous vascular lesion and benign cutaneous lesions.

Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, poikiloderma of Civatte and benign cutaneous lesion, such as warts, scars, striea and psoriasis.

Gynecology: Photocoagulation of benign cutaneous lesion and benign vascular lesion in gynecology

Podiatry: Treatment of benign cutaneous lesion, such as warts.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011092

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)